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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,864	04/27/2001	Martin M. Matzuk	P01925US2 (09807797)	1363

26271 7590 09/30/2002
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EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,864

Applicant(s)

MATZUK ET AL.

Examiner

Christopher S. F. Low

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) None is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

RESTRICTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a protein 01-236 (Npm2) nucleoplasmin is for example, classified in Class 530, subclass 350.
- 5 II. Claim 2, drawn to a polynucleotide (SEQ ID NO: 1) encoding the protein 01-236 (Npm2) nucleoplasmin is, for example, classified in Class 536, subclass 23.5.
- III. Claims 3-7, drawn to transgenic mice with a disruption of the genetic material (absent evidence to the contrary, this is different genetic material than 01-180 and 01-184) encoding the protein 01-236 (Npm2) nucleoplasmin are, for example,
10 classified in Class 800, subclass 18.
- IV. Claim 8-10, drawn to a method of making transgenic mice with a disruption of the genetic material encoding the protein 01-236 (Npm2) nucleoplasmin and breeding of same are, for example, classified in Class 800, subclass 21.
- V. Claims 11 and 12, drawn to transgenic mice with a disruption of the genetic material 01-180 (absent evidence to the contrary, is a different genetic material than 01-236 and 01-184), are, for example, classified in Class 800, subclass 18.
15
- VI. Claim 13 and 14, drawn to a method of making transgenic mice with a disruption of the genetic material 01-180 (absent evidence to the contrary, is a different genetic material than 01-236 and 01-184) and breeding of same are, for example, classified in Class 800, subclass 21.
20
- VII. Claim 15 and 16, drawn to a method of making transgenic mice with a disruption of the genetic material 01-184 (absent evidence to the contrary, is a different genetic material than 01-236 and 01-180) and breeding of same are, for example, classified in Class 800, subclass 21.
- 25 VIII. Claim 17 and 18, drawn to a method of making transgenic mice with a disruption of the genetic material or one or more of 01-236, 01-180 or 01-184 (absent evidence to the contrary, each is different genetic material one from the other) and breeding of same are, for example, classified in Class 800, subclass 21.

30 The inventions are distinct, each from the other for the following reasons:

The claims of groups I and II are independent and/or distinct one from the other because the protein and genetic material differ in physical, chemical, and biological properties (and functions) from a polynucleotide, e.g., a DNA or RNA.

35 In addition, the transgenic mice of groups III and V differ from the protein of group I as well as the polynucleotide of group II because (A) the protein is not a mouse and (2) the mice have genetic material that was deleted from the genome (thus, the mice would not be expected to have been able to produce the protein). Furthermore, the mice of each of groups III and V differ from the polynucleotide of group II because the mice do not have genetic material that was deleted from the genome which the genetic material claimed in group II.

40 In view of the foregoing, each of groups I, II, III and V differ from each other and are patentably distinct, one from the other. In addition, group I is patentably distinct and/or independent from each of groups IV and VI to VIII because the processes of use in each of groups IV

and VI to VIII are processes that delete genetic material from the product mice produced and therefore the mice do not or are not expected to have been able to produce nor have been the product defined in group I. Thus, group I differs from groups II through VIII.

5 Group II differs from the transgenic mice of groups III and V because the mice are not nor would have been expected to have the genetic material that was deleted. Thus, the products are different and patentably distinct. In addition, the mice are not substitutable for the genetic material deleted and the deleted genetic material is not substitutable as the mouse *per se*.

10 The inventions of groups IV and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the product of the process can be made by a different process. An alternative process is embodied in the claims of group IV which is traditional animal breeding technology which would produce mice with the deletion by mating the mice.

15 As to groups VI (01-180 genetic material) and VII (01-184 genetic material), each is a different process from the group IV (01-236 genetic material) process because the genetic material is, absent factual evidence to the contrary, different, one from the other. The products produced by the processes differ one from the other. Thus, groups IV, VI, and VII are patentably distinct.

20 The claims of group VIII appear to be a combination of groups IV, VI, and VII by recitation of a combination of deletions in the genome of the resultant product. Each of the processes of groups IV, VI, and VII are practicable individually and produce distinctly different products where the process of one of groups IV, VI or VII does not produce the resultant product on any one other group. Where the processes of groups IV, VI and VII are indicated in the claims of group VIII as subcombinations disclosed as usable together in a single combination of group VIII defining a
25 process to produce mice with one or two or three different deletion mutations in, absent factual evidence to the contrary, different genes used in the process result in distinct and/or patentably different products. The subcombinations of processes are distinct from each other because they are shown to be separately usable for the reasons indicated in the preceding paragraphs - any one or two of the deletion mutations (selected as 01-236 or 01-184 or 01-180 separately or 01-236/01-
30 180 or 01-236/01-184 or 01-184/01-180 do not do not result *per se* in any one other product.

In addition, the invention if group IV as has a separate utility based the statement in the application (page 6 - summary of the invention) that there are three (3) different genes, 01-236, 01-180, and 01-184 and that these genes encode three (3) different product (specification page 13, first paragraph of detailed description of the invention. The different processes of groups IV and VI
35 through VIII have separate utility such as producing mice with different fertility each from the other. See MPEP 806.05(d). Thus, each process is distinct and/or different, one from the other

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent

subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that for the response to this requirement to be complete the response must include an election of the invention to be examined even though the requirement is traversed
5 (37 C.F.R. 1.143). The response should include a statement as to:

- The selection of one of groups I through VIII;
- Where group VIII is elected, an election under 35 USC 121 of one of the combinations of 01-236 or 01-184 or 01-180 or 01-236/01-180 or 01-236/01-184 or 01-180/01-184 or 01-236/01/180/01-184 should be indicated as elected.


10 Note that where claims 17 and 18 are concerned, if the process of claims 17 and 18 are indicated as solely directed to a process of making transgenic mice where only one of 01-236 or 01-184, the examiner may consider rejoinder of group VIII to one of groups IV, VI, or VII if one of groups IV, VI or VII are elected. Claims 17 and 18 would be examined for patentability on the basis
15 of the elected material of group IV or VI or VII as well as patentability of the group VIII claims based on any other appropriate section of 35 U.S.C. 101, 112, 102 and 103.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under
20 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Low whose telephone number is (703) 308-2923. Inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

25 Papers related to this application may be submitted by facsimile transmission to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1) and must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The telephone number assigned to Art Unit 1653 in the CM1 PTO Fax Center is (703) 308-4242 or 305-3014.

30 CSFL
27 Sep 2002


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600